

EXHIBIT 8

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UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL : MDL NO. 1456
INDUSTRY AVERAGE WHOLESALE : CIVIL ACTION
PRICE LITIGATION : 01-CV-12257-PBS
THIS DOCUMENT RELATES TO :
U.S. ex rel. Ven-a-Care of : Judge Patti B. Saris
the Florida Keys, Inc. :
v. :
Abbott Laboratories, Inc., : Chief Magistrate
No. 06-CV-11337-PBS : Judge Marianne B.

Baltimore, Maryland

Friday, September 14, 2007

Videotaped Telephone Deposition of ROBERT NIEMANN

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<p>1 specific instance that you can recall in which 2 average wholesale price was used to refer to 3 something other than what was published in the 4 compendia?</p> <p>5 A. No. Other than to articulate that same 6 idea, that same concept.</p> <p>7 Q. Yes, sir. And in the various 8 conversations that you had with either Congress, 9 congressional representatives or congressional 10 staffers, was the term AWP or average wholesale 11 price, in your experience, used to refer to prices 12 published in Red Book and other compendia?</p> <p>13 A. Yes.</p> <p>14 Q. And in those various phone conversations, 15 there was never any confusion expressed about what 16 AWP referred to, that it is a published price, 17 correct?</p> <p>18 A. The context would have been clear.</p> <p>19 Q. And clear that it was the published price?</p> <p>20 A. Clear -- it would have been clear either 21 way. It would have been -- the context would have 22 been clear that we were talking about the Red Book</p>	<p>1 a little higher up, certainly over time. So there 2 were other individuals involved in it, IG personnel. 3 Q. What, if anything, do you recall about the 4 content of the conversations that you had with 5 Mr. Vito?</p> <p>6 A. Well, as I say, his findings. In other 7 words, he would be explaining the prices that he 8 found in his research, which ultimately were reported 9 in these various reports that he would issue.</p> <p>10 Q. Did you ever have any email communications 11 with Mr. Vito?</p> <p>12 A. I actually don't remember if we -- it 13 seems to me, we talked over the phone.</p> <p>14 Q. Anybody else at OIG that you can think of 15 that you communicated with?</p> <p>16 A. I know I did, like I would have spoken 17 with the data person who was running the data on the 18 report. That type of thing.</p> <p>19 Q. How about the GAO, the General Accounting 20 Office, did you ever have any communications with 21 anyone at GAO?</p> <p>22 A. Yes. That's fuzzier, but --</p>
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<p>1 AWP or not.</p> <p>2 Q. You mentioned the Office of Inspector 3 General. Do you recall having communications with 4 the Office of Inspector General relating to drug 5 payment policy issues?</p> <p>6 A. Yes. I'm -- yes, I know I did.</p> <p>7 Q. Who at OIG did you communicate with?</p> <p>8 A. Rob Vito.</p> <p>9 Q. What do you recall about your 10 conversations with Mr. Vito?</p> <p>11 MS. OBEREMBT: I'm going to object to the 12 extent that his conversations might contain 13 deliberative process information.</p> <p>14 THE WITNESS: His findings, more than 15 anything.</p> <p>16 BY MR. COOK:</p> <p>17 Q. How often did you speak to Mr. Vito?</p> <p>18 A. Occasionally.</p> <p>19 Q. Do you recall anybody else being on these 20 telephone calls?</p> <p>21 A. There were some other IG personnel who 22 were working on the same, I think -- I think Rob was</p>	<p>1 Q. Do you recall who at GAO you --</p> <p>2 A. I don't. And it seems to me, the two that 3 I remember in particular are both, they both retired 4 before I did.</p> <p>5 Q. What was the subject matter of your 6 communications with GAO?</p> <p>7 A. I honestly don't remember.</p> <p>8 Q. Do you recall communicating with anybody 9 on the White House staff relating to drug payment 10 issues?</p> <p>11 A. No, I don't.</p> <p>12 Q. How about at the various states. Any 13 state Medicaid programs? Do you recall communicating 14 with anyone?</p> <p>15 A. That would have been very occasional, 16 because in general, I didn't -- I didn't work on 17 policies that affected states.</p> <p>18 Q. Who at CMS was responsible for drug 19 payment issues on the Medicaid side?</p> <p>20 A. Well, the -- Larry Reed.</p> <p>21 Q. Would you communicate often with Mr. Reed 22 about drug payment policy issues?</p>

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<p>1 A. It's how I remember it.</p> <p>2 Q. Right. That HCFA had one alternative of</p> <p>3 estimated acquisition costs that would have allowed</p> <p>4 it, if implementable, to gauge the Medicare allowable</p> <p>5 amount to something closer than to actual acquisition</p> <p>6 cost, correct?</p> <p>7 A. Yes.</p> <p>8 Q. Was it your sense that HCFA as an</p> <p>9 organization wanted to move towards EAC?</p> <p>10 MS. OBEREMBT: Objection.</p> <p>11 THE WITNESS: I don't know how to answer</p> <p>12 that. I mean, you know, how many people would have</p> <p>13 been involved in this and what their opinions would</p> <p>14 have been, I never polled anybody.</p> <p>15 BY MR. COOK:</p> <p>16 Q. Okay. Was there anybody within the agency</p> <p>17 who preferred to stay with AWP rather than go to EAC</p> <p>18 in your memory?</p> <p>19 MS. OBEREMBT: Objection to the extent</p> <p>20 you're asking him about deliberative process</p> <p>21 conversations.</p> <p>22 THE WITNESS: So what do I do?</p>	<p>1 preferred to go with -- stay with AWP knowing that</p> <p>2 AWP exceeded acquisition costs, rather than going to</p> <p>3 EAC which would approximate acquisition costs, you're</p> <p>4 going to instruct him not to answer those questions?</p> <p>5 MS. OBEREMBT: I'm going to instruct him</p> <p>6 not to disclose discussions he had about what a</p> <p>7 policy should be, because that goes to the heart of</p> <p>8 the deliberative process privilege.</p> <p>9 MR. COOK: Well, I'll ask him a question</p> <p>10 and you can instruct him not to answer, because I</p> <p>11 just want this one to be -- I want to know what I can</p> <p>12 ask and what I can't. And I'll just go through the</p> <p>13 questions and you can instruct him not to answer</p> <p>14 them, if you think that they are not, you know,</p> <p>15 permissible.</p> <p>16 BY MR. COOK:</p> <p>17 Q. Mr. Niemann, you understood that there</p> <p>18 were essentially two options available to the</p> <p>19 Medicare program between 1991 and 1997 for</p> <p>20 establishing what the Medicare allowable should be or</p> <p>21 would be for physician administered drugs, correct?</p> <p>22 It's restating an earlier question. I know.</p>
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<p>1 MS. OBEREMBT: Why don't we take a break</p> <p>2 and let me find out what he was going to say.</p> <p>3 MR. COOK: Okay.</p> <p>4 THE VIDEOGRAPHER: This marks the end of</p> <p>5 tape three in the deposition of Robert Niemann.</p> <p>6 Going off the record. The time is 13:54:38.</p> <p>7 (Recess.)</p> <p>8 THE VIDEOGRAPHER: This marks the</p> <p>9 beginning of tape four in the deposition of Robert</p> <p>10 Niemann. Going back on the record. The time is</p> <p>11 14:02:57.</p> <p>12 MS. OBEREMBT: Chris, I understand your</p> <p>13 question to be asking him about discussions he had</p> <p>14 with others at CMS about what the drug policy should</p> <p>15 be.</p> <p>16 MR. COOK: Yes.</p> <p>17 MS. OBEREMBT: So on that basis, I'm going</p> <p>18 to instruct him not to answer because it does go to</p> <p>19 deliberative process.</p> <p>20 MR. COOK: And just so I know the</p> <p>21 parameters of the instruction not to answer, to the</p> <p>22 extent that there was anybody within CMS who actually</p>	<p>1 A. On the allowable, it's really technically,</p> <p>2 I guess, three.</p> <p>3 Q. Okay.</p> <p>4 A. Because we pay the lower of the actual</p> <p>5 charge on the --</p> <p>6 Q. All right. But there will always be a</p> <p>7 charge in connection with the claims for physician</p> <p>8 administered drug, correct?</p> <p>9 A. Right.</p> <p>10 Q. And the question is going to be, if that</p> <p>11 charge exceeds a certain amount, will you pay the</p> <p>12 charge or that certain amount, correct?</p> <p>13 A. Right.</p> <p>14 Q. So if, for example, the charge is -- well,</p> <p>15 I guess the last data point in any claim would be the</p> <p>16 actual cost to the physician, correct, although</p> <p>17 that's not one that you have.</p> <p>18 A. Well, all I was saying is that there are</p> <p>19 three.</p> <p>20 Q. Right.</p> <p>21 A. Components to the decision.</p> <p>22 Q. Correct. And if we were to look at an</p>

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<p>1 individual claim, there would be four, there would be 2 three data points, one would be the physician has an 3 actual cost, correct?</p> <p>4 A. Right.</p> <p>5 Q. You don't know what that is?</p> <p>6 A. Right.</p> <p>7 Q. The physician states a charge to the 8 program, correct?</p> <p>9 A. Right.</p> <p>10 Q. You do know what that number is?</p> <p>11 A. Yes.</p> <p>12 Q. And the program, through its carriers, has 13 an allowable amount which the charge may not exceed 14 or will be disallowed to the extent that it exceeds 15 the allowable, correct?</p> <p>16 A. They wouldn't pay any more than that.</p> <p>17 Q. Right. There were two options for the 18 program to set what the allowable amount would be 19 under the Medicare regulations as they existed 20 between 1991 and 1997, correct?</p> <p>21 A. Yes. I would just say, I would recognize 22 your struggle. The maximum allowable.</p>	<p>1 A. Yes. I think the carriers.</p> <p>2 Q. By either HCFA for its agent?</p> <p>3 A. Right.</p> <p>4 Q. Would calculate that number, correct?</p> <p>5 A. Yes.</p> <p>6 Q. And do you have an understanding of how 7 HCFA or its agents would calculate that number?</p> <p>8 A. No.</p> <p>9 Q. Do you have an understanding of what that 10 number would represent?</p> <p>11 A. Oh, as I said before, I think it would be 12 the best estimate of what the physician's acquisition 13 cost was. But I don't necessarily mean that 14 individual physician.</p> <p>15 Q. And in choosing between the published 16 average wholesale price and the best estimate of what 17 the physician's acquisition cost was, that is 18 estimated acquisition cost, did you have any 19 discussions within the agency about which option to 20 use?</p> <p>21 MS. OBEREMBT: You can answer that. You 22 can tell him whether or not you had discussions about</p>
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<p>1 Q. Precisely.</p> <p>2 A. Because it would never exceed the actual 3 charge.</p> <p>4 Q. Precisely.</p> <p>5 A. I get the drift of what you're saying.</p> <p>6 Q. And the two options for setting the 7 maximum allowable would be 100 percent of the average 8 wholesale price as published in Red Book or other 9 compendia, right?</p> <p>10 A. Or other compendia.</p> <p>11 Q. That's correct?</p> <p>12 A. Yes, I think that's what it said.</p> <p>13 Q. The other option available to the Medicare 14 program under the regulations was to establish an 15 estimated acquisition cost, correct?</p> <p>16 A. Yes.</p> <p>17 Q. Unlike the average wholesale price, that 18 would be a calculated number, correct?</p> <p>19 A. Yes.</p> <p>20 Q. It would be calculated by HCFA?</p> <p>21 A. I --</p> <p>22 Q. Or the carriers?</p>	<p>1 options.</p> <p>2 THE WITNESS: Yes.</p> <p>3 BY MR. COOK:</p> <p>4 Q. And were there individuals who advocated 5 for staying with the average wholesale price?</p> <p>6 MS. OBEREMBT: I'll direct you not to 7 answer that on the grounds of deliberative process.</p> <p>8 MR. COOK: So I can't get the foundation 9 of whether there were individuals who took that 10 position?</p> <p>11 MS. OBEREMBT: That's right. Because that 12 goes to the substance of the discussions. Your 13 previous went to whether or not there were 14 discussions. Now you're getting into the substance, 15 so I have to object.</p> <p>16 BY MR. COOK:</p> <p>17 Q. Were there individuals who advocated using 18 the estimated acquisition cost?</p> <p>19 MS. OBEREMBT: Objection. Grounds of 20 deliberative process. I'll instruct you not to 21 answer.</p> <p>22 BY MR. COOK:</p>

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<p style="text-align: center;">Page 198</p> <p>1 Q. Who participated in these discussions?</p> <p>2 A. It would have been my division director,</p> <p>3 me, and the deputy group director. Legislative</p> <p>4 personnel on our legislation staff. I don't mean --</p> <p>5 I don't mean staffers on the Hill. I mean our</p> <p>6 people. People like that.</p> <p>7 Q. When did these conversations take place?</p> <p>8 A. I guess off and on for the whole time that</p> <p>9 I was involved in it. Maybe not -- not too early. I</p> <p>10 don't have that clear recollection of --</p> <p>11 Q. As a matter of fact, for the entire time</p> <p>12 period where estimated acquisition cost was an option</p> <p>13 available to HCFA, HCFA in fact established its</p> <p>14 maximum allowable cost based upon average wholesale</p> <p>15 price, correct?</p> <p>16 A. Yes. Except where a carrier may have done</p> <p>17 it sooner than when this all came about with OMB and</p> <p>18 the information collection.</p> <p>19 Q. In any of these discussions, do you recall</p> <p>20 any participant ever expressing to you the belief</p> <p>21 that by paying average wholesale price, the Medicare</p> <p>22 program was reimbursing physicians at their actual</p>	<p style="text-align: center;">Page 200</p> <p>1 the deliberative process privilege. I'll instruct</p> <p>2 you not to answer.</p> <p>3 BY MR. COOK:</p> <p>4 Q. What position did you take about using</p> <p>5 average wholesale price or the estimated acquisition</p> <p>6 cost?</p> <p>7 MS. OBEREMBT: Objection on the grounds of</p> <p>8 deliberative process. I'll instruct you not to</p> <p>9 answer.</p> <p>10 BY MR. COOK:</p> <p>11 Q. Did politics ever play a role in the</p> <p>12 Medicare program's decision to continue to use</p> <p>13 average wholesale price rather than use estimated</p> <p>14 acquisition costs to establish its maximum allowable</p> <p>15 payment amount for drugs?</p> <p>16 MS. OBEREMBT: Objection to the extent</p> <p>17 you're asking him about discussions with agency</p> <p>18 personnel, where a policy decision was made. I have</p> <p>19 to instruct you not to answer that, too, I think.</p> <p>20 BY MR. COOK:</p> <p>21 Q. At various points in time between 1991 and</p> <p>22 1997, without telling me about what discussions were</p>
<p style="text-align: center;">Page 199</p> <p>1 acquisition cost?</p> <p>2 MS. OBEREMBT: Objection on the grounds of</p> <p>3 deliberative process. I'll instruct you not to</p> <p>4 answer.</p> <p>5 BY MR. COOK:</p> <p>6 Q. Has anybody ever in your time at HCFA</p> <p>7 expressed to you the belief that average wholesale</p> <p>8 price is a reliable indicator of the acquisition cost</p> <p>9 to physicians for drugs?</p> <p>10 MS. OBEREMBT: I'm going to object to the</p> <p>11 extent you're asking him about conversations he had</p> <p>12 that involve deliberative processes of the agency.</p> <p>13 I'm going to instruct you not to answer that, too.</p> <p>14 BY MR. COOK:</p> <p>15 Q. In any of these conversations relating to</p> <p>16 the possibility of abandoning AWP and going to</p> <p>17 estimated acquisition cost, did any of the</p> <p>18 individuals that you've described ever raise concerns</p> <p>19 about what the consequences would be to</p> <p>20 beneficiaries' access to care or other program goals</p> <p>21 of going to EAC?</p> <p>22 MS. OBEREMBT: Objection on the grounds of</p>	<p style="text-align: center;">Page 201</p> <p>1 made, is it fair to say the decision was made to stay</p> <p>2 with AWP and not go to estimated acquisition cost?</p> <p>3 A. Well, that was the stated, that was the</p> <p>4 regulation.</p> <p>5 Q. Well, the regulation allowed both.</p> <p>6 A. Oh, allowed both.</p> <p>7 Q. Yes.</p> <p>8 A. I'm sorry, would you repeat.</p> <p>9 Q. At various points in time, when the</p> <p>10 possibility of going from AWP to EAC was considered?</p> <p>11 A. Right.</p> <p>12 Q. In fact, HCFA continued to use AWP,</p> <p>13 correct?</p> <p>14 A. It did.</p> <p>15 Q. All right. After discussions relating to</p> <p>16 a possible change, and after it was decided to remain</p> <p>17 with AWP, did you ever have any discussions with any</p> <p>18 other personnel at HCFA about the decision that had</p> <p>19 already been made to stay with AWP, and whether that</p> <p>20 was a good idea?</p> <p>21 MS. OBEREMBT: Objection, because again I</p> <p>22 think you don't have a specific point demarcated.</p>

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<p style="text-align: center;">Page 202</p> <p>1 And his post policy discussions may be predecisional 2 to subsequent policies. So I can't -- I'm going to 3 object again on deliberative process, and instruct 4 you not to answer.</p> <p>5 BY MR. COOK:</p> <p>6 Q. Did you ever have any discussions with 7 anyone outside of HCFA about whether Medicare 8 could -- should continue to pay based upon AWP or 9 should use some other methodology for establishing 10 the maximum allowable amount?</p> <p>11 A. That I don't remember. Outside of HCFA?</p> <p>12 Q. Yes.</p> <p>13 A. I don't remember.</p> <p>14 Q. Say someone with Congress?</p> <p>15 A. That would have occurred. I can't 16 remember specifically, but that would have occurred.</p> <p>17 Q. Without the specifics --</p> <p>18 A. Not a member of Congress, but the staffer.</p> <p>19 Q. The staffer. Do you remember generally 20 what the subject matters were relating to the 21 possible departure from AWP as a methodology in your 22 conversations with congressional staffers?</p>	<p style="text-align: center;">Page 204</p> <p>1 MS. OBEREMBT: Are you asking him in his 2 conversations with people on the Hill?</p> <p>3 MR. COOK: Yes.</p> <p>4 MS. OBEREMBT: Okay. So focus your answer 5 on just conversations you had with people on the 6 Hill, what was said --</p> <p>7 THE WITNESS: Not HCFA people, but 8 staffers.</p> <p>9 MS. OBEREMBT: Right.</p> <p>10 BY MR. COOK:</p> <p>11 Q. Right. Did you or anybody else from HCFA 12 in these conversations with staffers on the Hill ever 13 advocate a change in the methodology away from AWP?</p> <p>14 A. Yes. Yes.</p> <p>15 Q. Why?</p> <p>16 MS. OBEREMBT: Objection. That goes to a 17 deliberative process issue, since you're asking him 18 why they would have expressed that opinion to the 19 staffers.</p> <p>20 MR. COOK: So the decision was whether to 21 talk to Congress?</p> <p>22 MS. OBEREMBT: You can ask him what was</p>
<p style="text-align: center;">Page 203</p> <p>1 A. I'm sorry. What was the -- what's the 2 crux of that? Do I remember what?</p> <p>3 Q. Do you remember generally what the subject 4 matters of those conversations were?</p> <p>5 A. Subject matters?</p> <p>6 Q. Let me ask it a little bit easier. Do you 7 remember anything at all about your conversations 8 with congressional staffers?</p> <p>9 A. That is easier. Not much, but it would --</p> <p>10 it would have been the IG information, and some kind 11 of methodology to pay a fair price.</p> <p>12 Q. Do you recall whether you or anybody else 13 from HCFA was advocating a change in the methodology 14 to these congressional staffers?</p> <p>15 MS. OBEREMBT: You can answer that.</p> <p>16 THE WITNESS: Was anybody advocating a 17 change to what the staffers were recommending? I'm 18 sorry.</p> <p>19 BY MR. COOK:</p> <p>20 Q. The status quo was that --</p> <p>21 A. AWP and we never implemented EAC. That 22 was the status quo.</p>	<p style="text-align: center;">Page 205</p> <p>1 said to the staffers, but you can't ask him why that 2 was said, because that does go to deliberative 3 process information, okay?</p> <p>4 MR. COOK: Just so I understand and I've 5 got the record straight, exactly which decision is 6 that deliberation predecisional to?</p> <p>7 MS. OBEREMBT: To decisions made within 8 the agency to either continue with the existing 9 policy or to proceed with change in policy. So why 10 don't you ask him what he said to the staffer -- or 11 was he present in any other HCFA meeting with a 12 congressional staffer.</p> <p>13 BY MR. COOK:</p> <p>14 Q. Did you express to the congressional 15 staffers why it was that HCFA was advocating a change 16 in the methodology by which Medicare paid for 17 physician administered drugs?</p> <p>18 A. Yes. I'm sure I would have expressed the 19 reason.</p> <p>20 Q. And what was that reason?</p> <p>21 A. It would have been the IG reports, the 22 fact that -- that at least some of the drugs under</p>

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<p style="text-align: center;">Page 206</p> <p>1 the AWP policy were -- we were paying too much. 2 Q. When you say too much, can you quantify 3 that for me? 4 A. No, I can't quantify it, because of the 5 reason you have cited, that it wasn't a single amount 6 with every drug. It varied. 7 Q. When you say too much, is that a dollar 8 amount, a percentage? 9 A. I remember that being some concern. And 10 remember being relieved that I wasn't the one who had 11 to pick the number. I mean, it's a judgment call 12 what -- like whether to knock off 5 percent or 15 13 percent, that's a judgment call. 14 Q. And 10 percent of a \$400 drug is a lot 15 more than a thousand percent of a \$2 drug, correct? 16 A. Indeed it is. 17 Q. Did you express to Congress any position 18 about what should be the appropriate reimbursement 19 amount for physician administered drugs? 20 A. I actually don't remember doing that. 21 Q. Did anybody, to your knowledge, express to 22 Congress what the appropriate reimbursement amount</p>	<p style="text-align: center;">Page 208</p> <p>1 average or a nondiscounted list price? 2 A. Not that I remember. 3 Q. And so when Congress in 1997 promulgated a 4 law requiring payment based at 95 percent of average 5 wholesale price, based upon your experience, would 6 you believe that Congress understood what average 7 wholesale price represented in Red Book? 8 MS. OBEREMBT: Objection. 9 MR. BATES: Object to form. 10 THE WITNESS: I don't know what you mean 11 when you say specifically understood what it 12 specifically represented. In other words, I think 13 they obviously felt that it was at least 5 percent 14 above what it should be. 15 BY MR. COOK: 16 Q. But did you ever in your conversations 17 with anybody within Congress have a congressional 18 staffer or congressional member express to you the 19 belief that average wholesale price was an actual 20 average of -- a calculated average of wholesale 21 prices? 22 A. I do not remember that.</p>
<p style="text-align: center;">Page 207</p> <p>1 should be for physician administered drugs? 2 A. I wouldn't know if somebody else did. 3 Q. But in the conversations that you 4 participated in, did anyone express an idea of what 5 should be the appropriate reimbursement amount? 6 A. I don't remember. 7 Q. Did you have discussions with -- do you 8 remember anything else at all about your 9 conversations with the congressional staffers? 10 A. Yes. 11 Q. What do you remember? 12 A. An interest in average sales price. 13 Q. Do you remember when this was? 14 A. No. I don't. 15 Q. Was it Congress that was expressing an 16 interest in average sales price or HCFA personnel? 17 A. I'm not sure where -- where it was 18 initiated, because some staffers were pretty well 19 informed, so it could have been either one. 20 Q. And in these conversations with 21 congressional staffers, was there any confusion about 22 whether published AWPs represented a calculated</p>	<p style="text-align: center;">Page 209</p> <p>1 Q. Other than -- well, can you remember 2 anything else about your conversations with 3 congressional staffers? 4 A. No. 5 Q. Do you remember what position the 6 congressional staffers took about what the 7 appropriate amount of reimbursement should be? 8 A. I don't think -- I don't. I mean, this 9 was a deliberation. I don't remember if they -- at 10 what point they arrived at a position. 11 Q. Were there any written documents used in 12 any of these meetings or conversations? 13 A. I only remember talking. I don't -- I 14 just don't remember. There could have been. I don't 15 remember. 16 Q. Other than Congress, were there any other 17 individuals outside of HCFA with whom you discussed 18 the issue of whether the Medicare program should use 19 some methodology other than AWP to establish 20 allowable amounts for prescription drugs? 21 A. If you consider Rob Vito of the IG -- is 22 that HCFA? I mean, I don't know. I might have</p>

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<p style="text-align: right;">Page 210</p> <p>1 talked about it with him. 2 Q. What did you discuss with Mr. Vito? 3 MS. OBEREMBT: I'm going to object on the 4 grounds of deliberative process. I'm going to 5 instruct you not to answer about your conversations 6 with Mr. Vito about whether HCFA should pursue a 7 different policy. 8 BY MR. COOK: 9 Q. Any other individuals outside of HCFA with 10 whom you discussed the possibility of using a 11 methodology other than AWP? 12 A. No. I don't remember. 13 Q. During your discussions within HCFA and 14 with Congress, both on whether or not the Medicare 15 program should use a methodology other than AWP to 16 establish allowable amounts, what information was 17 available to you and to the other participants in 18 those conversations? 19 A. Well, I remember the IG reports. That 20 was, that was the big thing. And other data that the 21 IG -- and don't ask me, I'm amazed I remember the 22 acronym. The acronym was NAMFUO and one of the</p>	<p style="text-align: right;">Page 212</p> <p>1 Q. Do you recall this particular OIG report 2 relating to the cost of dialysis related drugs? 3 A. No. 4 Q. You'll see that this one is addressed to 5 the acting administrator. In your experience, did 6 these reports, are these reports provided directly to 7 the administrator of HCFA? 8 A. I'm not sure I know what you mean. 9 Q. Or were they addressed to the 10 administrator of HCFA? 11 A. Yes. I think that was the protocol. 12 Q. And you'll see at the first paragraph of 13 the cover memo to Exhibit Abbott 82 that the report 14 was initiated at the request of HCFA following the 15 promulgation of the proposed rule that would have 16 paid for ESRD drugs at 85 percent of average 17 wholesale price. Do you see that? 18 A. I do. 19 Q. Is it your memory that in fact HCFA 20 requested the OIG to conduct reports following 21 promulgation of that rule? 22 A. No. I didn't remember that.</p>
<p style="text-align: right;">Page 211</p> <p>1 Medicaid people would probably know what that stands 2 for. I think the F was for fraud. Anyway, I 3 remember them generating some data. That's what I 4 remember. 5 Q. Any other data that you recall being part 6 of the consideration in these conversations? 7 A. That's all I remember. 8 Q. If I could get you to turn to Abbott 9 Exhibit 82. This is an October 20, 1992 OIG report 10 on the cost of dialysis related drugs. This is 11 addressed to William Toby, Jr., the acting 12 administrator of Health Care Financing 13 Administration. In 1992, your responsibilities 14 related to end stage renal disease, correct? 15 A. Yes. 16 Q. And it was approximately sometime in 1993, 17 was it early or late 1993? 18 A. Late. 19 Q. So approximately a year later, you took 20 over responsibility specifically for physician 21 administered drug reimbursement, right? 22 A. Yes.</p>	<p style="text-align: right;">Page 213</p> <p>1 Q. Do you have any reason to doubt that, in 2 fact, that occurred? 3 A. No. I have no reason to doubt that. 4 Q. Who at HCFA likely would have requested 5 the conduct of a report such as this by OIG? 6 A. That's a good question. It would have 7 been -- I'm not sure who it would have been. 8 Q. If I can get you to turn to page 6 of this 9 report. At the top, the OIG states that "under the 10 new drug regulation separately billable drugs would 11 be reimbursed based upon the lower of EAC or AWP." I 12 assume that's the regulation that you and I have been 13 talking about for a couple hours now, right? 14 A. Right. 15 Q. You'll see in the next two sentences that 16 the OIG indicates that it was determining an EAC 17 based upon surveys of actual invoice prices, and was 18 itself developing an EAC for the more frequently 19 administered separately billable drugs using median 20 invoice price obtained from 30 dialysis facilities, 21 so the second and third sentence of the first 22 paragraph?</p>

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<p style="text-align: right;">Page 214</p> <p>1 A. Right. 2 Q. Is that correct? 3 A. Yes. 4 Q. And the chart below provides data relating 5 to Calcijex, Inferon and Vancomycin. What is 6 Calcijex, do you know? 7 A. I forget. It's very familiar, but I 8 forget what the use was. It was a common drug for 9 dialysis patients. 10 Q. And the same for Inferon? 11 A. There again, I remember -- I remember the 12 name, but I don't remember what it was used for. 13 Q. And then Vancomycin, do you recognize that 14 as infusion antibiotic? 15 A. Yes. 16 Q. You'll notice that note two indicates that 17 "Calcijex and Inferon are single source drugs and 18 that Vancomycin is a multiple source drug," is that 19 consistent with your memory of these drugs? 20 A. I really don't have a memory on that 21 point. 22 Q. The chart prepared by the Office of</p>	<p style="text-align: right;">Page 216</p> <p>1 hard data on which you based policy decisions at 2 HCFA? 3 A. It would have counted. It was only 30 4 facilities, but it -- it's data. But I think people 5 would have been sensitive to the fact that it was 30 6 facilities. I guess we would leave it up to the 7 statisticians to tell us how significant that is. 8 Q. But you would agree with me that HCFA was 9 advised in 1992 that for at least these 30 10 facilities, Vancomycin was available at a median 11 acquisition cost of \$5 when its AWP was \$19.17, 12 correct? 13 A. Yes. 14 Q. Is this information that you would have 15 expected to come to you had you been the program 16 analyst in 1992 for physician administered drugs? 17 A. Well, I think what you meant to ask is for 18 ESRD related drugs, not physician administered drugs. 19 Q. Well, first, I was saying if you had been 20 the analyst -- 21 MS. OBEREMBT: Let him finish. 22 BY MR. COOK:</p>
<p style="text-align: right;">Page 215</p> <p>1 Inspector General goes on to describe the EAC and the 2 AWP as they have determined it for each of these 3 products. I'd like to focus on Vancomycin, which is 4 one of the drugs at issue in this case, Mr. Niemann. 5 A. Okay. 6 Q. What is it that OIG determined is the EAC 7 for Vancomycin? 8 A. According to the chart, \$5. 9 Q. And AWP, according to the OIG, was what? 10 A. \$19.17. 11 Q. Approximately four times the EAC, correct? 12 A. Yes. 13 Q. And if you'll look over a little bit, the 14 OIG indicates that 12 facilities were able to 15 purchase at or below \$5, correct? 16 A. Yes. 17 Q. And nine facilities were purchasing at or 18 above the EAC, correct? 19 A. Well, actually, that says above. 20 Q. Correct. 21 A. The at would be -- 9 would be above. 22 Q. Nine would be above. Is this the sort of</p>	<p style="text-align: right;">Page 217</p> <p>1 Q. I'm sorry. 2 A. This would have been more likely to come 3 to me as the ESRD reimbursement person. But 4 actually, either way, it probably would have come to 5 both of us. It would have come to people who 6 promulgated the proposed rule and it might have come 7 to me as well. 8 Q. And although you have no specific memory 9 of it, is this something that you would have expected 10 that you would have reviewed carefully when it came 11 to you? 12 A. Yes. 13 Q. Did you take any action with respect to 14 reimbursement for Calcijex, Inferon or Vancomycin as 15 a result of receiving this report, to your memory? 16 A. I don't remember that we did. 17 Q. Do you know whether anybody within HCFA 18 considered taking any action with respect to 19 reimbursement for any of these drugs as a result of 20 receiving this report? 21 MS. OBEREMBT: Could you repeat the 22 question, please?</p>

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<p style="text-align: right;">Page 218</p> <p>1 THE REPORTER: "Question: Do you know 2 whether anybody within HCFA considered taking any 3 action with respect to reimbursement for any of these 4 drugs as a result of receiving this report?</p> <p>5 MS. OBEREMBT: Chris, do you think you 6 could rephrase the question to ask whether he knows 7 if anybody took any action?</p> <p>8 MR. COOK: Well, I know nobody took any 9 action. I actually want to know whether they 10 discussed taking any action and decided not to.</p> <p>11 MS. OBEREMBT: Then I have to object based 12 on deliberative process, and I'll instruct you not to 13 answer.</p> <p>14 BY MR. COOK:</p> <p>15 Q. If I can get you to turn to appendix 2 of 16 the report, please. You see this is an array showing 17 the actual invoice price for the drugs studied by the 18 Office of Inspector General in this report, correct?</p> <p>19 A. Yes.</p> <p>20 Q. And again, I'd like to focus your 21 attention on Vancomycin because it's one of the drugs 22 at issue in this case. Correct me if I'm wrong, but</p>	<p style="text-align: right;">Page 220</p> <p>1 same product? No. I would not assume that.</p> <p>2 Q. Would you take from this data comfort that 3 reimbursing at AWP was a reliable proxy for provider 4 costs?</p> <p>5 A. No.</p> <p>6 Q. Vancomycin, as I indicated -- or as the 7 report indicates, is a multiple source drug as 8 indicated in this chart, as well as in the footnotes. 9 But do you have any reason to believe that other 10 injectable multiple source drugs had ranges or prices 11 that were any different than Vancomycin?</p> <p>12 MS. OBEREMBT: Objection.</p> <p>13 BY MR. COOK:</p> <p>14 Q. Do you have any reason to believe?</p> <p>15 A. Oh, I'm sorry. I shook my head. I have 16 no idea.</p> <p>17 Q. When you were the policy analyst, I keep 18 calling you program analyst, and I apologize.</p> <p>19 A. I think that might be more right. That 20 might be what it was.</p> <p>21 Q. When you were an analyst with a 22 responsibility for physician administered drugs, did</p>
<p style="text-align: right;">Page 219</p> <p>1 I believe the lowest price, invoiced price that the 2 OIG found for Vancomycin was \$3.45.</p> <p>3 A. That's the lowest number I see.</p> <p>4 Q. Yes. And that was, in fact, for a small 5 provider, correct?</p> <p>6 A. Yes.</p> <p>7 Q. And the highest price that anybody -- any 8 invoice reported to be paid for Vancomycin was 9 \$26.61, correct?</p> <p>10 A. Yes.</p> <p>11 Q. Would this indicate to you that Vancomycin 12 would be an example of a drug for which there was a 13 range of prices that providers were able to purchase 14 the drug at?</p> <p>15 A. To tell you the truth, if I saw this, I 16 would talk to the analyst who prepared the report.</p> <p>17 Q. Why is that?</p> <p>18 A. Because -- because that discrepancy is so 19 wide. I'm answering your question.</p> <p>20 Q. No. Please. Please.</p> <p>21 A. Would I assume from this report that this 22 was an accurate reflection of the variation in the</p>	<p style="text-align: right;">Page 221</p> <p>1 you ever ask the Office of Inspector General to 2 conduct further such reports gathering data upon 3 which estimated acquisition costs could be 4 determined?</p> <p>5 A. No. I don't ever remember doing that.</p> <p>6 Q. Do you know if anyone within HCFA asked 7 the Office of Inspector General to gather such data?</p> <p>8 A. I guess no, I don't know.</p> <p>9 Q. And you would agree with me from this 10 report that such an undertaking would at least have 11 been possible?</p> <p>12 MS. OBEREMBT: Objection.</p> <p>13 THE WITNESS: Such an undertaking? You 14 mean that the IG could have --</p> <p>15 BY MR. COOK:</p> <p>16 Q. Yes.</p> <p>17 A. What do you mean, was it possible that the 18 IG could have gotten more data?</p> <p>19 Q. Yes.</p> <p>20 A. I guess it was.</p> <p>21 Q. I mean, it certainly wasn't impossible for 22 HCFA to determine what the invoice prices were to</p>

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<p style="text-align: right;">Page 270</p> <p>1 re-examine its Medicare drug reimbursement 2 methodologies with the goal of reducing payments as 3 appropriate. Do you see that?</p> <p>4 A. Yes, I do.</p> <p>5 Q. What was HCFA's response to that?</p> <p>6 A. Well, I'm reading it here. I wouldn't 7 have remembered but this does sort of jar my memory. 8 It says, we agree with the OIG's findings and 9 recommendations. We included a provision in the 10 president's 1998 budget bill. That would have been 11 President Clinton -- I kind of remember that -- that 12 would have eliminated the markup for drugs billed to 13 Medicare by requiring physicians to build a program 14 for the actual acquisition costs for drugs.</p> <p>15 Q. And that -- that provision was not 16 enacted, was it?</p> <p>17 A. Right. That's the last sentence. 18 Unfortunately, this provision was not enacted, but 19 we'll pursue this policy in appropriate ways.</p> <p>20 Q. And then the last of the OIG reports that 21 I'd like to ask you about is attached as Exhibit 94. 22 This is the January 2001 --</p>	<p style="text-align: right;">Page 272</p> <p>1 oranges. I have that isolated memory, but I don't 2 really remember the specific report.</p> <p>3 Q. What do you remember generally about 4 looking at the prices obtained by the VA under the 5 federal supply schedule?</p> <p>6 A. That it was a totally different system.</p> <p>7 Q. How so?</p> <p>8 A. They had purchasing power, and I think the 9 VA actually purchased the drugs and distributed to 10 their facilities, if I remember right. It's just a 11 different, a whole different system.</p> <p>12 Q. Was there ever any consideration of using 13 the information available from the federal supply 14 schedule to adjust Medicare reimbursement levels?</p> <p>15 MS. OBEREMBT: Objection. On the grounds 16 of deliberative process, I'll instruct you not to 17 answer.</p> <p>18 BY MR. COOK:</p> <p>19 Q. Mr. Niemann, you are aware that the VA and 20 the federal supply schedule existed, correct?</p> <p>21 A. Yes.</p> <p>22 Q. How long were you aware of that?</p>
<p style="text-align: right;">Page 271</p> <p>1 MS. OBEREMBT: Hold on. He doesn't have 2 the exhibit.</p> <p>3 BY MR. COOK:</p> <p>4 Q. I'm just putting it on the record. Just 5 for the record, this is a January 2001 OIG report 6 entitled "Medicare reimbursement of prescription 7 drugs." And while you take a look at that particular 8 report, tell me whether or not you recall it, I will 9 mark as Exhibit Abbott 313, a document that I'll ask 10 you to take a look at.</p> <p>11 (Exhibit Abbott 313 was 12 marked for identification.)</p> <p>13 BY MR. COOK:</p> <p>14 Q. And do I take from Exhibit Abbott 313 that 15 you attended an exit conference for the OIG report 16 that's marked as Exhibit 94?</p> <p>17 A. Yes. It looks that way.</p> <p>18 Q. Do you remember this particular OIG 19 report?</p> <p>20 A. No. Well, I remember the issue of looking 21 at the Department of Veterans Affairs, because 22 that -- that, as I remember, was like apples to</p>	<p style="text-align: right;">Page 273</p> <p>1 A. I don't remember. Mr. Vito would have 2 told me that and I don't remember when that was.</p> <p>3 Q. Leaving aside what deliberations went into 4 it, in fact, the Medicare program never used that 5 data to adjust their reimbursement levels, correct?</p> <p>6 A. Well, it was AWP.</p> <p>7 Q. At that point it was AWP, based on the 8 statute, correct?</p> <p>9 A. Oh, right. In 2000, it was. Actually, it 10 was some reduction of AWP, I guess.</p> <p>11 Q. Was it 95 percent of AWP?</p> <p>12 A. Did it change again? I don't remember.</p> <p>13 Q. Whatever it was, it was?</p> <p>14 A. Whatever it was.</p> <p>15 Q. Yes, sir. Why don't we take a five-minute 16 break, and I'll line up some exhibits so we can move 17 through efficiently.</p> <p>18 THE VIDEOGRAPHER: Going off the record.</p> <p>19 The time is 15:58:52.</p> <p>20 (Recess.)</p> <p>21 THE VIDEOGRAPHER: Going back on the 22 record. The time is 16:09:40.</p>

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UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

- - - - - - - - - - - - - - -x
In re: PHARMACEUTICALS INDUSTRY : MDL No. 1456
AVERAGE WHOLESALE PRICE : Civil Action
LITIGATION : 01-CV-12257-PBS
:
THIS DOCUMENT RELATES TO: : Judge Patti B.
United States of America, ex : Saris
rel. Ven-a-Care of the Florida :
Keys, Inc., :
vs. : Chief Magistrate
ABBOTT LABORATORIES, INC., : Judge Marianne
No. 06-11337-PBS : B. Bowler
- - - - - - - - - - - - - - -x

Baltimore, Maryland

Thursday, October 11, 2007

Continued Videotaped Deposition of ROBERT NIEMANN

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|--|---|
| <p>1 Q. What did you understand to be the
2 consequences of the issuance of program
3 memorandum AB-00-86?</p> <p>4 A. If a carrier considered any of these
5 data, as I recall, it would have lowered the
6 Medicare payment allowance for that drug.</p> <p>7 Q. What was the consequence of withdrawing
8 AB-00-86 on November 17, 2000?</p> <p>9 A. Well, I remember the agency being very
10 clear that it was a suspension, and that's the
11 term they specifically used, they suspended it.
12 What was the consequence?</p> <p>13 Q. Yes.</p> <p>14 A. I guess it basically would have
15 remained in place whatever the payment allowances
16 were.</p> <p>17 Q. In your description of carrier
18 discretion before, would it be true that even in
19 the absence of Exhibit Abbott 184, which is
20 transmittal AB-00-86, that carriers would have
21 been authorized to consider information such as
22 this in calculating AWPs?</p> | <p>1 for the deliberations that aren't being revealed?
2 MS. OBEREMBT: You asked him the
3 motivation.</p> <p>4 MR. COOK: Uh-huh.</p> <p>5 MS. OBEREMBT: Unless it's stated in
6 this document, I don't think he can discuss
7 internal deliberations within the agency that
8 aren't reflected in this document.</p> <p>9 BY MR. COOK:</p> <p>10 Q. Are there internal deliberations
11 relating to this document that you would have to
12 reveal in order to answer my question?</p> <p>13 A. I think so. If it's not stated in
14 here, then anything I know -- yes, yes.</p> <p>15 Q. Among who -- among whom did those
16 deliberations take place?</p> <p>17 A. My chain of command and analysts in the
18 Office of Legislation.</p> <p>19 Q. Anyone else?</p> <p>20 A. All internal. It would all have been
21 HCFA people.</p> <p>22 Q. You didn't have any discussions with</p> |
| Page 478 | Page 480 |
| <p>1 MS. OBEREMBT: Objection.</p> <p>2 A. I'm not really -- I'm not really in a
3 position to know that.</p> <p>4 Q. Do you know why it was that CMS issued
5 Exhibit Abbott 184?</p> <p>6 A. Usually that's in the program
7 memorandum itself. Is it not in there? Oh, the
8 purpose, thank you, is to provide you with an
9 alternative source of average wholesale price
10 data.</p> <p>11 Q. As counsel pointed to you, that
12 certainly is the stated purpose of the program
13 memorandum. I'm asking you why, the motivation
14 for issuing the program memorandum.</p> <p>15 MS. OBEREMBT: I'm going to object to
16 the extent you're trying to get at deliberative
17 process information. If you can answer without
18 referring to something covered by the
19 deliberative process privilege, please do so.</p> <p>20 THE WITNESS: I don't think I can.</p> <p>21 MS. OBEREMBT: Okay.</p> <p>22 MR. COOK: Could I get the foundation</p> | <p>1 anyone at the Department of Justice about whether
2 to issue this program memorandum?</p> <p>3 A. I don't remember that, but I don't
4 think the agency would have -- I don't remember
5 that.</p> <p>6 Q. The program memorandum, Exhibit Abbott
7 184, refers to the National Association of
8 Medicaid Fraud Control Units, NAMFCU.</p> <p>9 A. Right.</p> <p>10 Q. N-A-M-F-C-U; is that correct?</p> <p>11 A. Yes.</p> <p>12 Q. Did you discuss with NAMFCU why this
13 program memorandum was being issued?</p> <p>14 A. I don't remember ever talking with that
15 -- that they were -- no, I don't remember talking
16 with anyone there.</p> <p>17 Q. Is there anything else you recall about
18 the deliberations that form the basis for
19 counsel's instruction not to -- not to answer my
20 last question?</p> <p>21 MS. OBEREMBT: He did just answer your
22 last question.</p> |

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|---|--|
| <p>1 data; not to some selection process that went
2 into the program memorandum.</p> <p>3 Q. Well, the question -- the premise of
4 the question, am I correct, is that some brand
5 names and some NDC numbers used by the DMERCs
6 were not included on Attachment 1 to the program
7 memorandum, correct?</p> <p>8 A. Yeah, that's what I would surmise from
9 that too.</p> <p>10 Q. And so your answer was that HCFA wasn't
11 the one who chose which to include, but DOJ and
12 NAMFCU were, correct?</p> <p>13 A. Yeah. I'm being a little picky here.
14 I don't think you meant the way I took it. I
15 don't think the DOJ chose which NDCs to go into
16 the program memorandum. I think they chose which
17 NDCs to report to us. We didn't tell Justice
18 which NDCs we wanted them to report to us. See
19 what I'm saying? So ultimately I think what I
20 meant by this, what I would have meant was that
21 the data in the PM came from DOJ.</p> <p>22 Q. But your answer says specifically that</p> | <p>1 and you indicated that you would provide guidance
2 and subsequent correspondence concerning future
3 updates. Do you see that?</p> <p>4 A. I do.</p> <p>5 Q. What was HCFA's plan for providing
6 future guidance? Was it to get additional data
7 from DOJ and pass it on?</p> <p>8 A. I don't remember that we had a plan.</p> <p>9 Q. Did anyone within the agency oppose the
10 issuance of transmittal AB-00-86?</p> <p>11 MS. OBEREMBT: Objection, calls for
12 deliberative process.</p> <p>13 MR. COOK: Would that be an instruction
14 not to answer?</p> <p>15 MS. OBEREMBT: Why don't you ask him if
16 he remembers any discussions with people in the
17 agency, because if he doesn't remember anything,
18 I don't need to instruct him not to answer.</p> <p>19 MR. COOK: How about I ask him the
20 question I asked him. I can ask another one
21 later.</p> <p>22 MS. OBEREMBT: All right. Well, let me</p> |
| Page 526 | Page 528 |
| <p>1 HCFA did not choose the products in the program
2 memorandum, correct?</p> <p>3 A. Yeah, right, it didn't choose the data.
4 Obviously HCFA would have made the choice if we
5 were not going to publish any part of the data
6 that we received in the PM, we would have decided
7 that, but I don't think we did, and based on
8 this, we didn't.</p> <p>9 Q. Is it your understanding that HCFA
10 published all of the data that the DOJ and NAMFCU
11 provided to it?</p> <p>12 A. That's what I would take this to mean,
13 right.</p> <p>14 Q. And in fact, in the next question, when
15 the DMERCs asked how HCFA determined what
16 strength, what form, what quantity and what
17 packaging to use, you again referred to DOJ and
18 NAMFCU as determining those questions, right?</p> <p>19 A. Right.</p> <p>20 Q. The last question in -- in this list of
21 questions from the DMERCs asks whether HCFA is
22 going to update this information in the future,</p> | <p>1 go confer with him.</p> <p>2 MR. COOK: Go off the record.</p> <p>3 THE VIDEOGRAPHER: This marks the end
4 of Tape 4 Volume 2 in the deposition of Robert
5 Niemann, going off the record. The time is
6 15:46:48.</p> <p>7 (Recessed at 3:46 p.m.)</p> <p>8 (Reconvened at 4:00 p.m.)</p> <p>9 (Exhibit Abbott 356 and Exhibit
10 Abbott 357 were marked for identification.)</p> <p>11 THE VIDEOGRAPHER: This marks the
12 beginning of Tape 5 Volume 2 in the deposition of
13 Robert Niemann, going back on the record. The
14 time is 16 and 30 seconds.</p> <p>15 BY MR. COOK:</p> <p>16 Q. Mr. Niemann, the court reporter has
17 handed you what she has marked Exhibit Abbott
18 356. Although before that, let's get the answer
19 to the question that I had pending. I apologize.
20 Let me ask it one more time, see where we stand.
21 Did anybody at the agency, Mr. Niemann, oppose
22 the issuance of AB-00-86?</p> |

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